

Safety Data Sheet

IODOFLEX™ Dressing

1. Identification

1.1. Product identifier

Product Identity IODOFLEX™ Dressing
Alternate Names 0.9% Cadexomer Iodine Wound Dressing

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use Unit-dose paste with gauze backing for the treatment of chronic exuding wounds
Application Method See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name Smith & Nephew
970 Lake Carillon Drive, Suite 110
St. Petersburg, FL 33716

Emergency

Customer Service: Smith & Nephew 1-800-876-1261

2. Hazard(s) identification

2.1. Classification of the substance or mixture

STOT SE 3;H335 May cause respiratory irritation.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.



Warning

H335 May cause respiratory irritation.

[Prevention]:

P261 Avoid breathing dust / fume / gas / mist / vapors / spray.
P271 Use only outdoors or in a well-ventilated area.

[Response]:

P304+312 IF INHALED: Call a POISON CENTER or doctor / physician if you feel unwell.
P340 Remove victim to fresh air and keep at rest in a position comfortable for breathing.

[Storage]:

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P403+233 Store in a well ventilated place. Keep container tightly closed.

P405 Store locked up.

[Disposal]:

P501 Dispose of contents / container in accordance with local / national regulations.

3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Pregelatinized Starch CAS Number: 0009005-25-8	50 - 75	Not Classified	[1][2]
Polyethylene glycol CAS Number: 0025322-68-3	50 - 75	STOT SE 3;H335	[1]
Iodine CAS Number: 0007553-56-2	1.0 - 10	Acute Tox. 4;H332 Acute Tox. 4;H312 Aquatic Acute 1;H400	[1][2]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

*The full texts of the phrases are shown in Section 16.

4. First aid measures

4.1. Description of first aid measures

General

In all cases of doubt, or when symptoms persist, seek medical attention.
Never give anything by mouth to an unconscious person.

Inhalation

Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

Eyes

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

Skin

No first aid should be needed. If rash or other symptoms develop, discontinue use and consult a physician.

Ingestion

Call a physician or poison control center for instructions. Do not induce vomiting unless directed to do so by medical personnel.

4.2. Most important symptoms and effects, both acute and delayed

Overview

Acute Effects

Eye: May be irritating to eyes.

Skin: May cause allergic skin reaction in individuals sensitive to iodine.

Ingestion: Swallowing may cause abdominal discomfort, headache, nausea, and vomiting.

Medical Conditions Aggravated by Long-Term Exposure

Individuals with thyroid disorders may be at increased risk from exposure.

Chronic Effects

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Chronic absorption of iodine may result in iodism with symptoms of hyper salivation, sneezing, conjunctivitis, laryngitis, headache, skin rash and gastric upset. May affect thyroid function.

See section 2 for further details.

Inhalation

May cause respiratory irritation.

5. Fire-fighting measures

5.1. Extinguishing media

Water spray, carbon dioxide, dry chemical, foam

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

Wear self-contained breathing apparatus and protective clothing.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Small Spills: Wipe up with absorbent material and place in a container for disposal.

Large Spills

Containment: Contain spill using an inert absorbent material. Do not permit spilled material to enter sewers or waterways.

Cleanup: Wear appropriate protective clothing and equipment. Collect with an inert absorbent and place in a suitable container for disposal. Clean spill area with water and collect for proper disposal.

7. Handling and storage

7.1. Precautions for safe handling

Wash thoroughly after handling. Avoid contact with eyes.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

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Incompatible materials: Iodine reacts with powdered aluminum, active metals, acetylene, acetaldehyde and ammonium hydroxide.

Store in a cool, dry place < 77°F / 25°C.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

8.1. Control parameters

Exposure

CAS No.	Ingredient	Source	Value
0007553-56-2	Iodine	OSHA	C 0.1 ppm (1 mg/m ³)
		ACGIH	Ceiling: 0.1 ppm Revised 2008; 2010,
		NIOSH	C 0.1 ppm (1 mg/m ³)
		Supplier	No Established Limit
0009005-25-8	Pregelatinized Starch	OSHA	TWA 15 mg/m ³ (total) TWA 5 mg/m ³ (resp)
		ACGIH	TWA: 10 mg/m ³
		NIOSH	TWA 10 mg/m ³ (total) TWA 5 mg/m ³ (resp)
		Supplier	No Established Limit
0025322-68-3	Polyethylene glycol	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
		Supplier	No Established Limit

Carcinogen Data

CAS No.	Ingredient	Source	Value
0007553-56-2	Iodine	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;
0009005-25-8	Pregelatinized Starch	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

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0025322-68-3	Polyethylene glycol	OSHA	Select Carcinogen: No
		NTP	Known: No; Suspected: No
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No; Group 4: No;

8.2. Exposure controls

Respiratory	If workers are exposed to concentrations above the exposure limit they must use the appropriate, certified respirators.
Eyes	Protective safety glasses recommended
Skin	Gloves and protective clothing are recommended.
Engineering Controls	Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.
Other Work Practices	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

Appearance	Gauze backing with a reddish-brown Paste
Odor	Faint
Odor threshold	Not determined
pH	3 - 5 @ 20°C
Melting point / freezing point	Not determined
Initial boiling point and boiling range	Not determined
Flash Point	Not classified as flammable or combustible
Evaporation rate (Ether = 1)	< 1 (nBuAc = 1)
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not applicable Upper Explosive Limit: Not applicable
Vapor pressure (Pa)	1.0 mmHg @ 38°C (iodine)
Vapor Density	8.8 (iodine) (Air = 1)
Specific Gravity	0.8 @ 25°C (H ₂ O = 1)
Solubility in Water	Forms a gel
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not determined
Decomposition temperature	Not available
Viscosity (cSt)	Not determined
VOC Content	Not available
% Volatile	0

9.2. Other information

No other relevant information.

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10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Open flames, excessive heat (> 200°F)

10.5. Incompatible materials

Iodine reacts with powdered aluminum, active metals, acetylene, acetaldehyde and ammonium hydroxide.

10.6. Hazardous decomposition products

Thermal decomposition may include carbon dioxide, carbon monoxide, hydrocarbons, iodine.

11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Pregelatinized Starch - (9005-25-8)	No data available	No data available	No data available	No data available	No data available
Polyethylene glycol - (25322-68-3)	30,200.00, Rat - Category: NA	20,000.00, Rabbit - Category: NA	No data available	No data available	No data available
Iodine - (7553-56-2)	No data available	No data available	No data available	No data available	No data available

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable

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STOT-single exposure	3	May cause respiratory irritation.
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

The preparation has been assessed following the conventional method of the Dangerous Preparations Directive 1999/45/EC and GHS and is not classified as dangerous for the environment, but contains substance(s) dangerous for the environment. See section 3 for details

Aquatic Ecotoxicity

Ingredient	96 hr LC50 fish, mg/l	48 hr EC50 crustacea, mg/l	Er C50 algae, mg/l
Pregelatinized Starch - (9005-25-8)	Not Available	Not Available	Not Available
Polyethylene glycol - (25322-68-3)	1,000.00, Salmo salar	Not Available	Not Available
Iodine - (7553-56-2)	Not Available	Not Available	Not Available

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable

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14.4. Packing group Not Applicable Not Applicable Not Applicable

14.5. Environmental hazards

IMDG Marine Pollutant: No

14.6. Special precautions for user

No further information

15. Regulatory information

Regulatory Overview The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Toxic Substance Control Act (TSCA) All components of this material are either listed or exempt from listing on the TSCA Inventory.

WHMIS Classification Not Regulated

US EPA Tier II Hazards

Fire: No

Sudden Release of Pressure: No

Reactive: No

Immediate (Acute): Yes

Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

Antimony trioxide

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%):

Iodine

Pennsylvania RTK Substances (>1%):

Iodine

Pregelatinized Starch

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16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H312 Harmful in contact with skin.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

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